K073293

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5- 510(k) Summary.

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Name of contact person: Jean-Francois Durette, e-mail: jfdurette@oculoplastik.com

October 16th, 2007

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of device evaluation
Document Mail CenterHFZ-401
9200 Corporate Blvd.
Rockville, Maryland, 20850 USA

Re: 510(k) Submission
The Durette Implant
from Oculo-Plastik, Inc.

Attention: Document Control Clerk

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted at least 90 days prior to the date when OCULO-PLASTIK, INC., proposes to introduce into the U.S. market for commercial distribution an enucleation implant to be known as the Durette Implant from Oculo-Plastik, Inc.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: SPHERE, EYE IMPLANT (CODE 86 HPZ)
   Common/Usual Name: Durette Implant
   Trade/Proprietary Name: Durette Implant .

2. Establishment Registration #: 8022166

3. SPHERE, EYE IMPLANT, have been reviewed by the FDA Ophthalmology Device Classification Panel. The code (86 HPZ) has been assigned by FDA. Class II.

4. No performance standards applicable to SPHERE, EYE IMPLANT, have been assigned by FDA.

5- Oculo-Plastik is claiming substantial equivalence to the original Allen implant and the Oculo-Plastik implants namely the Iowa, New Allen, Universal, and acrylic sphere implants.

6- Description of the device.

6.a Scientific concepts that form the basis for the device.

The Durette Implant's design and features were elaborated by myself (a Board Certified Ocularist) and analyzed by many ophthalmologists and ocularists (artificial eye makers). There must have been at least 30 collaborators since the start of the project in 2003-04. Throughout these years of

development, they gave feedback as it progressed.

What motivated the design and features of the Durette implant in 4 models came from my own experience fabricating custom ocular prostheses for patients for over 30 years and the understanding of the needs of the surgeons who will be installing these, as well as the knowledge of the consequences for the patient who now have to live with their implant and their prosthesis. It also came from discussions with many surgeons and colleague ocularists about the many implants and their respective features, advantages and disadvantages.

It is well admitted that a majority of ophthalmic surgeons want spheres. Because generally, it is easy to fabricate a mobile prosthesis with a normal looking anterior chamber over a shrunken globe, I imagined creating a quasi-spherical implant that would behave as an implant, just like if it was a shrunken globe. It would offer improved motility over a spherical implant, yet be similar to a sphere. With impression molding, it is possible to avoid the unsightly rotation and slippage behind the prosthesis common in sockets with true sphere implants, especially when not wrapped. I conceived an implant that would not necessarily need wrapping and to which the surgeon could easily suture the muscles to, at different levels, to allow some flexibility in surgery.

As soon had I shown the prototype to surgeons, some said they wanted more front details, as they felt it would improve coupling and motility. They are the minority who value details for coupling. So I created a second model. One with which we can expect the socket irregularities will be minimal, after the rectus muscles are in place, yet still obtain more coupling details. It is my personal ocularist experience that some details are not a problem. After showing these first 2 models to a few more surgeons at the American Academy of Ophthalmology (AAO) and at the American Society of ocularist (ASO) conference, some expressed the fear of any details at all while others wanted still more details for coupling. So if I wanted this type of acrylic implant to become a success, I believe I would have to create two more models. A third model with the least details possible I could imagine would still avoid unsightly rotation often seen in a sphere. A fourth model with still more details, yet less than an Iowa Implant with high mounds. I wanted to respond to all the surgeons' preferences while assuring these implants would be a great implant for the ocularist to fabricate a prosthesis and the patient to live with and be happy.

A patient is best served when a device caters to the needs and considerations of the surgeon, that of the ocularists and that of the patient having to live with it. Some of the aspects, as it relates to an implant, for a happy patient are: a quiet, well-filled and least disturbed socket, optimal lid positioning as well as optimal and practical motility of the prosthesis, stability of the implant within the socket and resulting prosthetic stability.

The configuration of the 4 models of the Durette Implant, each surgeon choosing it's model of preference, should appeal to most physicians, as it was designed for their appreciation. The same applies for ocularists. The smooth features will prove beneficial for ocular prosthesis fabrication and stability in the socket. The design of this implant will offer the ocularist adequate space between the posterior wall of the socket and the eyelids to fit a well functioning and comfortable ocular prosthesis or artificial eye.

The design will also offer motility in all simplicity. In comparison to a porous implant that is offered with an absorbable coating, the Durette implant is a mobile implant that will keep it's smooth surface permanently.

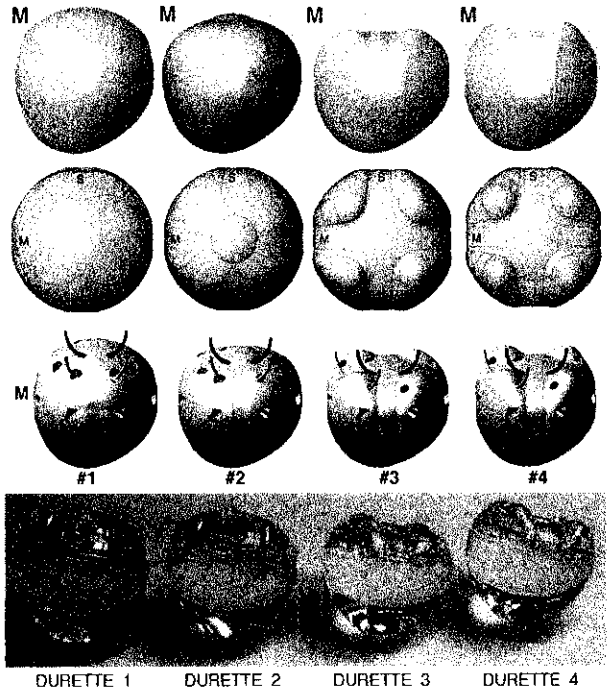
6.b How the device functions.

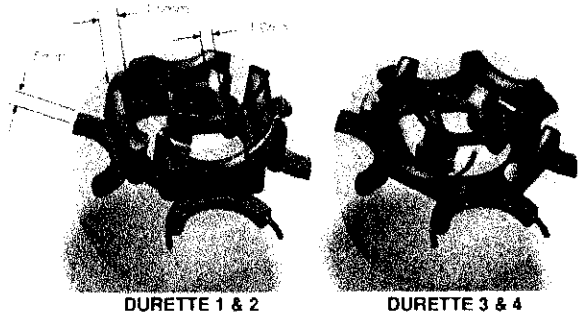
The surgeon chooses one of the 4 (it should now have been sterilized by the hospital) models and its' size of the Durette implant (an acrylic implant). The position of the off-center medial elongation, to fill more of the cavity, is established before the sutures and muscles are attached to the most appropriate location to get a good frontal position of the implant details in the socket. Once tissues are well closed, a supplied conformer is placed in the socket.

The implant having a network of 20 interconnected tunnels for suturing, these tunnels serve as well for tissue ingrowth. The invading tissue help stabilize the implant in place before the sutures have absorbed. When the socket is ready, an impression is taken of the resulting ocular socket and an ocular prosthesis is fabricated (preferably custom made).

7- Significant physical and performance characteristics of the device;

7.a Device design.





Proposed conformers for

#1 and 2 #3 and 4.

To be able to distinguish how each model is made:
The #1 is as spherical as possible; it has a slight double radius front and is 1 mm flatter on the anterior surface than a sphere of equal diameter.
The #2 also has double radius front plus minute details to resemble a phthisical globe.
The #3 has low mounds like a severely shrunken globe (offering more coupling than the #2).
Finally the #4 has still higher mounds, although the mounds remain well within a sphere.

Each Durette ocular implant has a smooth surface to give less likelihood of eroding through the covering tissue. Each has tunnels to allow direct suturing of the muscles. They all offer the surgeon a choice of 3 positions for each rectus muscle. The 20 interconnected tunnels of 1 to 2mm, all situated in the anterior 3rd of the implant, allow tissue integration. Even if all 20 holes are not used, they will always serve as interconnected tunnels for ingrowth to help stabilize the implant.

Each model has an off-center elongation into the apex of the orbit, for more volume and to help placement of front details. The medial posterior elongation is slight so it should not interfere with motility. The front details being well inside an imaginary sphere contour, they should allow sufficient space for the prosthesis with as normal an anterior chamber as possible.

The implants will be supplied with conformers adequate to the implant front details.

7.b Material used.

The Durette Implant will be made with the same acrylic material we already mold our other acrylic implants.

The Durette Implants being molded in 2 parts to make the tunnels, these parts need to be welded. There is an addition in material in a liquid to serve during the welding process. This liquid partly dissipates in the process, but some remain in a dry form on the surface of the implant. This liquid was chosen for it's biocompatibility and because it was an implantable liquid (in a dry state).

7.c Physical properties.

Acrylic is a durable well-known biocompatible implant material.

8- Intended use of the device.

The Durette ocular acrylic (PMMA) implants in 4 models are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and to impart motion and stability to the eventual ocular prosthesis. The indications are the same as those of the predicate devices. So it will not affect the safety and effectiveness of the device when used as labeled.

9- Summary of how the technological characteristics of your device compare to the predicate devices.

Like all the predicate devices, the Durette is made in acrylic. They are all smooth-surfaced. The Durette implant in 4 models is quasi-spherical and as such all models are more conservative in design than the Allen, the Iowa, the New-Allen and the Universal implants.

On the other hand, the Durette models are not a pure spheres, but their quasi-spherical characteristics makes then well within an imaginary contoured sphere, except for the slight medial off-center elongation.

In addition to enuleaction, the Durette implant is adequate also for evisceration and secondary implantation, which was not the case for the Allen, the Iowa and New Allen implants, but was the case for the Universal and the acrylic sphere implants.

The Durette has tunnels, similarly to those of the Universal. They too allow suturing and should also allow tissue ingrowth.

Acrylic spheres, since they offer no suturing tunnels nor tissue ingrowth may migrate, unless they are wrapped to allow suturing the muscles to the wrapping. Although the Durette could be wrapped, it is not neccessary as they have the tunnels for suturing and for ingrowth.

As for the surgery, all implants can benefit from the best surgical techniques.

10- Non-clinical tests performed.

Assembled implants are inspected and tested for their conformance to our specifications. Our implants are produced under our Quality Assurance System. Oculo-Plastik Inc. is ISO 13485 (2003) and ISO 9000.

A mold test was done to validate that the tunnels are as specified and that suggested needle would pass well inside the suturing tunnels.

After the welding process was developed, pull-tests were done to establish that proper acrylic welding was obtained consistently.

11- Clinical data performed.

No clinical trials were made with this estimated equivalent implant device.

12- Summary about non-clinical and clinical test for the Durette implants.

It is not felt any clinical trials would be needed, as this implant is rather a consolidation of all previously used implants, cumulating all the advantages and possibly none of the disadvantages. It is felt the Durette will be as safe or safer, be as effective or more, and perform as well or better than the predicate devices.

As for non-clinical tests, we make sure they are made as specified in our documentation as per our numerous Certifications of our Quality Assurance System, including ISO 9000 and 13485 (2003).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Oculo Plastik, Inc.
c/o Mr. Jean-Francois Durette, President
200 W. Sauvé
Montréal, Québec
Canada H31 1Y9

MAR 19 2008

Re: K073293
Trade/Device Name: Durette Implant
Regulation Number: 21 CFR 886.3320
Regulation Name: Shphere, Eye Implant
Regulatory Class: II
Product Code: HPZ
Dated: February 25, 2008
Received: February 26, 2008

Dear Mr. Durette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4- Indication for Use Statement

510(K) number unknown.

Device name: Durette Implant

Indications For Use:

The Durette ocular acrylic (PMMA) implants in 4 models are permanent implants that occupy the eye cavity when it becomes necessary to surgically remove the eye (enucleation), the contents of the eye sac (evisceration), or space left after the removal of another ocular implant (used as a secondary implant). It is used to replace volume and to impart motion and stability to the eventual ocular prosthesis.

Prescription Use: YES
(Part 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K073293